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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,514	03/31/2004	John R. Gilbert	TGZ-030	9911
959	7590	09/29/2005	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/816,514

Applicant(s)

GILBERT ET AL.

Examiner

Krishnan S. Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11 and 13-60 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 8, 19-44, 51 and 53-58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17, 18, 45-50, 52 and 59 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 11, 13, 14 and 60 is/are rejected.
- 7) ☒ Claim(s) 7, 10, 15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-8,10,11 and 13-60 are pending as of 7/15/05, of which claims 4,5,8,19-44, 51 and 53-58 are withdrawn from consideration.

#### ***Claim Objections***

Claim 6 is objected to because of the following informalities: Claim 6 is missing "includes a" in the first line before "a first connector" due to an inadvertent deletion.

Appropriate correction is required.

Claim 15 is objected to because the claim recites "the capping further includes", (which should be "the capping module further includes"), is considered as an inadvertent error. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,6,11,13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Campbell et al (US 2003/0215941).

Claims 1: Campbell teaches a microfluidic system or a molecular fractionation device (figures 3,6,7,9 and 10) microchannels (abstract, paragraph 46, see figure 7 and 9) on substrate, communication ports (eg., "compound administration port" and

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“metabolite detection” in figure 9), capping module (“insert”, figure 9) having an affinity matrix (caco-2) and a trapping filter with semipermeable membrane (porous substrate with PDMS membrane – figure 6) for compartmentalizing the matrix, capping module is stacked on to the substrate (figures).

Claims 6: capping module includes chamber for the matrix and connector ports – fig 6,7,9,10

Claim 11: see figures 3,6,7,9,10 for the capping module with substrate, matrix and the filter.

Claim 13: the microwell in figure 6 includes a port (open top) in communication with the substrate through the membrane in figure 7 or 9 as claimed.

Claim 14: substrate includes first and second connector ports – see figures.

Claim 60: sealable matrix insertion port – see figure 6 and 9. The open top of the well is sealable.

2. Claims 11,13 and 14 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Anderson et al (US 2002/0015952).

Anderson teaches a capping module comprising a substrate forming several recesses, a matrix of immobilized agents (paragraph 88, figure 4), a trapping membrane (24; also see paragraph 152) covering the recess (microtiter well). Substrate includes several connector ports extending through the membrane (one open top for each well)

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell as applied to claim 1 above and further in view of Wilding et al (US 5,498,392).

Instant claims differ from the teaching of Campbell in the recitation of the affinity beads coated with binding cites. Wilding teaches affinity beads with binding cites in a microfluidic system (see column 14 lines 38-60). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Wilding in the teaching of Campbell for the microtiter plate for applications such as PCR as taught by Wilding.

#### ***Allowable Subject Matter***

17,18, 45-50, 52 and 59 are allowed.

Claims 7,10,15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Claim 10: The closest prior arts are Campbell'941, Wilding'392 and Geli'354. These references do not teach or suggest having a semipermeable membrane as a

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trapping filter for compartmentalizing the matrix with the membrane covered by an impermeable layer except for the first and second connection ports.

Claim 7: The prior arts do not teach a second connector port extending through the semi-permeable membrane in the capping module for connecting the chamber in communication with a second microchannel to the surface of the substrate.

Claims 45-50,52: The prior arts do not teach a microfluidic system with the plurality of molecular fractionation devices having the side wall to include a semipermeable membrane as claimed and being in a series arrangement as claimed.

Claims 15 and 59: The prior arts do not teach a microfluidic system having a capping module with a recess or compartment sealed on one side with a semi-permeable membrane, and having the first, second, third and fourth connectors in communication with respective microchannels as claimed.

Claim 17 and 18: The prior arts do not teach a microfluidic system having a capping module with a trapping filter and the first, second, third and fourth connector ports connecting the respective microchannels through the respective valves.

### ***Response to Arguments***

Applicant's arguments with respect to claims 11-3,6,11,13 and 14 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S. Menon  
Patent Examiner  
9/21/05

  
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